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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/091,912	03/05/2002	Richard R. Bott	GC724	9189

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JANET KAISER CASTANEDA  
GENENCOR INTERNATIONAL, INC.  
925 PAGE MILL ROAD  
PALO ALTO, CA 94304-1013

EXAMINER

STEADMAN, DAVID J

ART UNIT PAPER NUMBER

1656

DATE MAILED: 04/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/091,912

Applicant(s)

BOTT ET AL.

Examiner

David J. Steadman

Art Unit

1656

**– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 09 February 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1,19,28,30,31 and 33-50 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,19,28,30,31 and 33-50 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>6/9/05</u> | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Status of the Application***

**[1]** The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1656.

**[2]** Claims 1, 19, 28, 30-31, and 33-50 are pending in the application.

**[3]** Applicant's amendment to the claims, filed on 2/9/2006, is acknowledged. This listing of the claims replaces all prior versions and listings of the claims.

**[4]** Applicants' arguments filed on 2/9/2006 have been fully considered and are deemed to be persuasive to overcome some of the rejections and/or objections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

**[5]** The text of those sections of Title 35 U.S. Code not included in the instant action can be found in a prior Office action.

### ***Claim Rejections - 35 USC § 112, Second Paragraph***

**[6]** The rejection of claims 1, 19, 28, 30-31, and 33-50 as being indefinite in the recitation of "wild-type *Pseudomonas mendocina* cutinase" or "wild-type *P. mendocina* cutinase" is maintained for the reasons of record and the reasons stated below. The rejection was fully explained in a prior Office action.

RESPONSE TO ARGUMENT: Applicant argues the definition of the term "wild-type" is disclosed in the specification at p. 6, ll. 30-31, and that in view of this definition,

a skilled artisan would recognize the metes and bounds of the terms “wild-type *Pseudomonas mendocina* cutinase” and “wild-type *P. mendocina* cutinase.”

Applicant's argument is not found persuasive. The definition “wild-type” as given in the specification is “a precursor protein from which a variant is derived.” This definition encompasses not only those proteins that occur “naturally,” but also encompasses mutant and variant proteins that are themselves precursors prior to further mutation. As such, it is unclear as to the scope of polypeptides that are intended as being encompassed by the terms “wild-type *Pseudomonas mendocina* cutinase” and “wild-type *P. mendocina* cutinase.” Consequently, it is unclear as to the scope of claimed cutinase variants.

***Claim Rejections - 35 USC § 112, First Paragraph***

[7] The new matter rejection of claims 1, 19, 31, 34-41, 44, and 46-50 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record and the reasons stated below. The rejection was fully explained in the prior Office action.

RESPONSE TO ARGUMENT: According to applicant, support for the limitation of increased polyesterase activity and enhanced thermostability can be found at Tables 1-3 of the specification. However, this is not found persuasive because, while Tables 1-3 may support specific “species” of variants having increased polyesterase activity and enhanced thermostability, the “species” of Tables 1-3 do not support all members of the “genus” of cutinase variants as encompassed by the claims. As stated in previous Office actions, the claims encompass cutinase variants having mutation at position 192 and

194 *and any other amino acid*. It is noted that applicant has amended the claims to recite the transitional phrase “consisting essentially of” in place of “comprising.” MPEP § 2111.03 states, “[a] ‘consisting essentially of’ claim occupies a middle ground between closed claims that are written in a ‘consisting of’ format and fully open claims that are drafted in a ‘comprising’ format” and that “absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, ‘consisting essentially of’ will be construed as equivalent to comprising.” In this case, in accordance with MPEP § 2111.03, the examiner has interpreted the transitional phrase “consisting essentially of” as meaning “comprising.” Applicant is invited to show support for the limitation at issue in the claims.

**[8]** The written description rejection of claims 1, 19, 28, 30-31, and 33-50 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record and for the reasons stated below. The rejection was fully explained in a prior Office action.

RESPONSE TO ARGUMENT: Applicant notes the claims have been amended to replace the transitional phrase “comprising” with “consisting essentially of.”

Applicant’s amendment is acknowledged, however, the amendment fails to overcome the written description rejection. It is noted that applicant does not attempt to explain how those cutinase variants “consisting essentially of” a substitution distinguish from those variants that “comprise” a substitution. As noted above, the term “consisting essentially of” has been construed as “comprising.” Thus, at least for the reasons of record, the rejection is maintained. Accordingly, the examiner has broadly, but

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reasonably interpreted the claims as being drawn to a genus of cutinase variants having mutation at position 192 and 194 *and any other amino acid of SEQ ID NO:2*. In view of this broad but reasonable interpretation, it is the examiner's position that the claimed genus of cutinase variants is not adequately described by the specification.

**[9]** The scope of enablement rejection of claims 1, 19, 28, 30-31, and 33-50 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record and for the reasons stated below. The rejection was fully explained in a prior Office action.

RESPONSE TO ARGUMENT: Applicant argues the amendment to replace the transitional phrase "comprising" with "consisting essentially of" renders the rejection moot.

Applicant's argument is not found persuasive. It is noted that applicant does not attempt to explain how those cutinase variants "consisting essentially of" a substitution distinguish from those variants that "comprise" a substitution. The amendment fails to overcome the instant rejection because, as noted above, the term "consisting essentially of" has been construed as "comprising." Thus, at least for the reasons of record, the rejection is maintained. Accordingly, the examiner has broadly, but reasonably interpreted the claims as being drawn to a cutinase variant having mutation at position 192 and 194 *and any other amino acid of SEQ ID NO:2*. In view of this broad but reasonable interpretation, it is the examiner's position that undue experimentation is required to make and use the full scope of claimed cutinase variants. Further, it is noted that the examiner's position that there is a high level of unpredictability in making all

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cutinase variants as encompassed by the claims is supported by applicant's instant response, which states (in relevant part), "[a]t the time the invention was made it was well established that altering amino acid sequences could result not only in differences in expression and secretion levels of the protein but also alter the properties of the protein" and that because "[i]t is very likely that altering the amino acids in the catalytic region would result in a decrease in the enzymatic activity or thermostability...one skilled in the art would not have a reasonable expectation of success in altering the amino acid sequence as presently claimed...would enhanced thermostability and/or polyesterase activity" (instant response at p. 11, bottom). Thus, in accordance with applicant's statement, while a skilled artisan would have an expectation of success for obtaining cutinase variants having enhanced thermostability and/or polyesterase activity by mutating SEQ ID NO:2 according to those specifically disclosed embodiments, one of skill in the art would not have an expectation of success for obtaining such variants at other positions of SEQ ID NO:2.

***Claim Rejections - 35 USC § 103***

**[10]** The rejection of claim(s) 1, 28, 30, 33-39, and 41-50 under 35 U.S.C. 103(a) as being unpatentable over Poulouse et al. (US Patent 5,352,594) is maintained for the reasons of record and the reasons stated below. The rejection was fully explained in a prior Office action.

RESPONSE TO ARGUMENT: Applicant argues there is no teaching or suggestion to modify the polypeptide at the recited positions to arrive at a variant having

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increased polyesterase activity and/or thermostability. Applicant argues the suggestion of Poulouse et al. to replace the amino acids within 6 amino acids on either side of the catalytic triad amino acids (corresponding to amino acids 140, 220, and 190 of SEQ ID NO:2) is at best an invitation to try. Applicant argues there is no direction from Poulouse et al. as to which if any amino acid within 6 amino acids of the catalytic triad could be replaced with the other 19 amino acids that would result in increased polyesterase activity and/or thermostability. According to applicant, it is likely that altering the catalytic triad amino acids would decrease enzyme activity or thermostability and thus an ordinarily skilled artisan would have no expectation of success that altering these amino acids would enhance polyesterase activity and/or thermostability.

Applicant's argument is not found persuasive. Poulouse et al. teach that it would be useful to modify *Pseudomonas mendocina* cutinase in order to alter its perhydrolysis/hydrolysis ratio,  $k_{cat}$ , and  $K_m$  (column 2, lines 52-54). In order to do this, Poulouse suggest altering "about six amino acids on either side of a catalytic amino acid" of *P. mendocina* cutinase (column 5, lines 42-57). Poulouse et al. identify Ser126, Asp176, and His206 (as acknowledged by applicant, correspond to amino acids 140, 190, and 220, respectively, of SEQ ID NO:2 herein) as the *P. mendocina* cutinase catalytic triad amino acids (column 7, lines 12-14). Poulouse et al. suggest replacing each of the amino acids within six of the catalytic triad with the 19 other amino acids to select for those that have the "best ratio or substrate specificity" (column 6, lines 41-47). This a clear suggestion to make all single amino acid variants within six amino acids of the catalytic triad. Thus, in making the variants as suggested by Poulouse et al., one



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would have made the position 192 and 194 variants with any amino acid at either of these positions, which would inherently have increased polyesterase activity and/or thermostability. While it is acknowledged that Poulouse et al. did not specifically seek to increase polyesterase activity and/or thermostability, as noted in the prior Office action, MPEP § 2144 makes clear that “[i]t is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant.”

Although applicant argues that one of ordinary skill in the art would have expected that mutations as suggested by Poulouse et al. would decrease catalytic activity or thermostability, it is noted that applicant provides no objective evidence to substantiate this assertion. Further, it is noted that Poulouse et al. provides the working example of a Ser205 mutant (corresponding to a Ser219 of SEQ ID NO:2) that disputes applicant's assertion. Poulouse et al. teaches that mutation of Ser205, which is within the six amino acids of His206 of the cutinase of Poulouse et al., with various other amino acids does not disrupt catalytic activity (see, *e.g.*, columns 11-16). Further, Poulouse et al. teach that multiple substitutions within the six amino acids of the catalytic triad “can be done to optimize the results” (column 6, lines 47-49) and show working examples of double mutants, comprising mutation of Ser205 and another amino acid position within six amino acids of the catalytic triad, which maintain catalytic activity (columns 15-18). Thus, in making the double-mutant variants as suggested by Poulouse et al., one would have made the position 192 or 194 and 219 variants with any amino acid at positions 192/219 or 194/219, which would inherently have increased polyesterase activity and/or thermostability. Thus, in view of the teachings of Poulouse et al., it is the examiner's

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position that the claimed invention would have been obvious to one of ordinary skill in the art at the time of the invention.

### ***Conclusion***

**[11]** Status of the claims:

- Claims 1, 19, 28, 30-31, and 33-50 are pending.
- Claims 1, 19, 28, 30-31, and 33-50 are rejected.
- No claim is in condition for allowance.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Steadman whose telephone number is 571-272-0942. The examiner can normally be reached on Mon to Thurs, 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David J. Steadman, Ph.D.  
Primary Examiner  
Art Unit 1656